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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/584,555

05/31/00

SORRELLI D

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1399-1-02101

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HNJ 2/0925

EXAMINER

SUBTITLE	
ART UNIT	PAPER NUMBER

1635  
DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/584 586

Applicant(s)

SORRENTINO ET AL

Examiner

Eleanor Sorbello

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-15, drawn to a method of performing *ex-vivo* expansion of a gene modified hematopoietic stem cell, encoding an ABC transporter, classified in class 424, subclass 93.21.
  - II. Claims 14-21, drawn to method of engrafting a mammal with a gene modified hematopoietic stem cells encoding an ABC transporter, classified in class 424, subclass 93.21.
  - III. Claims 22-26, drawn to a method of identifying a stem cell wherein detection is performed with an antibody that binds to BCRP, classified in class 424, subclass 130.1
  - IV. Claims 27, 28, drawn to a method of diagnosing acute myelogenous leukemia (AML) by determining the expression of BCRP in a leukemic cell, classified in class 536, subclass 23.5.
2. Inventions I and II are related as process of making, and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claims will be examined along with the elected invention (MPEP § 806.05(i)).

3. Bunting et al. teach Hematopoietic Cells transduced with MDR1. (Bunting, K. "Transduction of Murine Bone Marrow Cells with an MDR1 vector enables Ex vivo stem cell expansion, but these expanded grafts cause a Myeloproliferative syndrome in transplanted mice. (Blood: vol. 92, No. 7 (Oct. 1, 1998) pages 2269-2279).

4. Inventions I and II are distinct from Inventions III and IV.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 86.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I and II are drawn to methods wherein hematopoietic stem cells encoding an ABC transporter are expanded, and transplanted, whereas Invention III is drawn to a method of identifying a stem cell that expresses BCRP wherein the detection is performed with an antibody, and Invention IV is drawn to a method of diagnosing AML in a human subject by determining the expression of BCRP. Therefore, each of inventions I and II are distinct from Inventions III and IV.

5. Invention III and IV are distinct because Invention III is drawn to a method of identifying a stem cell that expresses BCRP wherein the detection is performed with an antibody whereas Invention IV is drawn to a method of diagnosing AML in a human subject. The inventions III and IV are therefore distinct.

6. Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other group, restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleanor Sorbello whose telephone number is 703-308-6043. The examiner can normally be reached on M-F: 6.30AM-3.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3230 for regular communications and 703-305-3230 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Art Unit: 1633

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September 21, 2001

*Scott D. Priebe*  
SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER